Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: **Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443-1984.

Comments are invited on: (a) the proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915-0327) - Revision

Section 602 of Pub. L. 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(9) of the PHS Act to notify manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program while maintaining efficiency, transparency and integrity, the HRSA Office of Pharmacy Affairs (OPA) developed a process of registration of covered entities to enable it to address those mandates.

Enrollment/Registration

To enroll and certify the eligible federally funded grantees and other safety net health care providers, OPA requires entities to submit administrative information (e.g., shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate grantee level or entity level authorizing officials and state/local government representatives. The purpose of this registration information is to determine eligibility for the 340B Drug Pricing Program. This information is entered into the 340B database by entities and verified by OPA staff according to 340B Drug Pricing Program requirements. Accurate records are critical to implementation of the 340B Drug Pricing Program, especially to prevent drug diversion to non-eligible individuals as well as duplicate discounts from manufacturers. To maintain accurate records, OPA also requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program. The burden requirement for these processes is low for recertification and minimal for submitting change requests.

Contract Pharmacy Self-Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are also required to submit general information about the arrangements and certifications that signed agreements are in place with those contract pharmacies.

The annual estimate of burden is as follows:

Reporting Requirement	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
HOSPITAL ENROLLMENT, ADDITIONS & RECERTIFICATIONS					
340B Program Registrations & Certifications for Hospitals	546	1	546	2.0	1092
Certifications to Enroll Hospital Outpatient Facilities	606	1	606	.50	303
Hospital Annual Recertifications	4842	1	4842	.50	2421
REGISTRATIONS AND RECERTIFICATIONS FOR ENTITIES OTHER THAN HOSPITALS					
340B Registrations for Community Health Centers	253	1	253	1.0	253
340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types	353	1	353	1.0	353
Community Health Center Annual Recertifications	4507	1	4507	.50	2253.5

Family Planning Annual Recertifications	3879	1	3879	.50	1939.5
STD & TB Annual Recertifications	2754	1	2754	.50	1377
Annual Recertification for Entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics	1174	1	1174	.50	587
OTHER INFORMATION COLLECTIONS					
Submission of Administrative Changes for any Covered Entity	2500	1	2500	.50	1250
Submission of Administrative Changes for any Manufacturer	350	1	350	.50	175
CONTRACTED PHARMACY SERVICES REGISTRATION & RECERTIFICATIONS					
Contracted Pharmacy Services Registration	2500	1	2500	1.0	2500
TOTAL	24,264		24,264		14,504

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 13, 2012

Reva Harris

Acting Director, Division of Policy and Information Coordination

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